PATENT
Attorney Docket No. 29,225

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 4,626,538

Granted: December 2, 1986

For: [7-(3-Disubstituted Amino)phenyl] pyrazolo [1,5-a]pyrimidines

Assignee: Wyeth (formerly American Home Products Corporation)

Recorded: May 1, 2002 at Reel 012822 / Frame 0248

Commissioner for Patents and Trademarks
Box Patent Extension
Washington, DC 20231

HAND CARRY TO:
KARIN FERRITER
OFFICE OF PATENT LEGAL ADMINISTRATION
CRYSTAL PLAZA 3-3D09

Sir:

COMMENT ON FDA REGULATORY REVIEW PERIOD CALCULATION

Applicant hereby submits this comment on FDA's October 2, 2001 calculation of the regulatory review period for the approved drug product SONATA® (zaleplon) ("Sonata") in connection with the patent term extension application for U.S. Patent No. 4,626,538 (the "'538 patent"). The following has recently come to applicant's attention in the course of preparing an application for interim extension of the patent term.

On October 5, 1999, applicant filed a patent term extension application under 35 U.S.C. § 156 for the '538 patent. In its application, applicant noted that the Investigational New Drug Application ("IND") for zaleplon was submitted to FDA on April 16, 1991, and used an IND effectiveness date of

May 16, 1991 – 30 days after the submission date – for purposes of calculating the length of the IND phase of the Sonata regulatory review.

By letter dated October 2, 2001 to the Commissioner of Patents, FDA set forth its determination of the regulatory review period. In its calculation, FDA rejected the IND effectiveness date set forth in the patent term extension application and used instead an earlier date of May 2, 1991 as the date on which the IND became effective. FDA's explanation was:

> The applicant claims May 16, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 2, 1991, which was thirty days after FDA receipt of the IND.

Applicant's internal records support an IND submission date of April 16, 1991. The copy of the IND in Applicant's files is dated April 16, 1991 and it bears a stamp showing receipt by the FDA on April 18, 1991. FDA's April 24, 1991 acknowledgment of receipt of the IND also refers to the date of submission of the IND as April 16, 1991. The date of receipt of the IND set forth in the April 24 acknowledgment is April 22, 1991. Other documents, such as the New Drug Application submitted for Sonata on December 30, 1997, similarly refer to the IND as having been submitted on April 16, 1991.

The information that applicant has does not necessarily contradict FDA's assertion that the IND first became effective on May 2, 1991. Under FDA's regulations, while an IND ordinarily becomes effective 30 days after receipt by FDA, FDA may determine that an IND is effective earlier. 21 C.F.R. § 312.40(b)(2).

Applicant notes that Applicant's records do not indicate whether, pursuant to early FDA notice, the IND in fact went into effect on May 2, 1991, as

FDA concluded in its October 2, 2001 regulatory review period calculation. Applicant's records do show, however, that the IND was effective no later than May 21, 1991 because, in a letter from FDA to Lederle (a division of American Cyanamid) dated June 14, 1991, FDA stated that "[w]e have completed our review of your submission, as amended on May 13, 1991, and, as communicated to you by Mr. Merrill Mille in a telephone conversation held on May 21, 1991, have concluded that you may proceed with your proposed clinical investigation."

The pertinent information of which applicant is aware regarding the date of effectiveness of the IND is as follows:

4/16/91	Submission to FDA of initial IND for zaleplon
4/18/91	Stamped date of receipt of IND by FDA
4/22/91	Date of receipt of IND set forth in FDA's April 24, 1991 letter acknowledging receipt of the IND
5/13/91	Submission to FDA of protocol amendments to IND
5/21/91	Telephone conversation with Mr. Merrill Mille of FDA communicating the Agency's conclusion that proposed clinical investigation may proceed, as confirmed by June 14, 1991 letter from FDA to IND sponsor.

Respectfully submitted,

Dated: March 21, 2003

By: _____

Arnold S. Milowsky
Attorney for Applicant
Reg. No. 35,288
Telephone: (610) 902-2635

PATENT
Attorney Docket No. 29,995

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 4,626,538

Granted: December 2, 1986

For: [7-(3-Disubstituted Amino)phenyl] pyrazolo [1,5-a]pyrimidines

Assignee: Wyeth (formerly American Home Products Corporation)

Recorded: May 1, 2002 at Reel 012822 / Frame 0248

MAIL STOP PATENT EXTENSION
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

HAND CARRY TO:
Karin Ferriter
Office of Patent Legal Administration
Crystal Plaza 3-3D09

Sir:

CHANGE OF ATTORNEY'S ADDRESS IN APPLICATION AND COMMENT REGARDING NOTICE OF FINAL DETERMINATION

In follow-up to the request for interim extension of patent term filed by Applicants on March 21, 2003 for the above-identified patent, it came to Applicants' attention on May 16, 2003 that a Notice of Final Determination had been mailed by the USPTO on March 4, 2003. Applicants were able to obtain a copy of this Notice of Final Determination for the first time on May 19, 2003. From the Notice of Final Determination, it appears that an old correspondence address was used for mailing the Notice of Final Determination to Applicants.

Applicants note that the correct customer number and correspondence address have been associated with the U.S. patent application file for US 4,626,538 well before the mailing of the Notice of Final Determination. The following paper is being submitted, however, to ensure that the same correspondence address for the patent application file of US 4,626,538 is used for correspondences related to the patent term extension file for US 4,626,538, and to clarify that at the time Applicants filed the request for interim extension of patent term, they were unaware that a Notice of Final

Determination had been issued.

Although Applicants are not requesting that the 30-day time period for requesting reconsideration of the patent term extension be reset in the Notice of Final Determination, Applicants direct attention to the "Comment on FDA Regulatory Review Period Calculation" that was filed by Applicants on March 21, 2003 with the request for interim extension of patent term. It is noted that this document was filed within the 30-day period set forth in the Notice of Final Determination, and should more appropriately be treated as being a comment in response to the Notice of Final Determination.

With respect to the correspondence address, please send all further correspondence for the captioned application for patent term extension as follows:

☒ Customer Number: 25291

Bar Code:

OR

☐ Wyeth
Patent Law Department
Five Giralda Farms
Madison, NJ 07940
Attention:

Please direct all further telephone calls to:
Name: Kimberly R. Hild
Tel. No. 610-902-2628

While no fees are considered necessary for this change of correspondence address, the Commissioner is hereby authorized to charge any fees that may be required to deposit account no. 01-1300.

Respectfully submitted,

Arnold S. Milowsky
Attorney for Applicants
Reg. No. 35,288
Telephone: 610-902-2635

Dated: 5/23/03

Wyeth
Patent Law Department
Five Giralda Farms
Madison, NJ 07940

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Washington, DC 20231

HAND CARRY TO:
KARIN FERRITER
OFFICE OF PATENT LEGAL ADMINISTRATION
CRYSTAL PLAZA 3-3D09

Sir:

LETTER OF TRANSMITTAL FOR REQUEST FOR INTERIM EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156(e)(2) AND 37 C.F.R. § 1.760

Transmitted herewith are the following documents:

Request For Interim Extension Of Patent Term; and
Comment on FDA Regulatory Review Period Calculation.

While no fees are considered necessary for this request for an interim extension, the Commissioner is hereby authorized to charge any fees that may be required to deposit account no. 01-1300.

Respectfully submitted,

Dated: March 21, 2003

By: _____

Arnold S. Milowsky
Attorney for Applicant
Reg. No. 35,288
Telephone: 610-902-2635

500557

PATENT
Attorney Docket No. 29,225

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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HAND CARRY TO:
KARIN FERRITER
OFFICE OF PATENT LEGAL ADMINISTRATION
CRYSTAL PLAZA 3-3D09

Sir:

REQUEST FOR INTERIM EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156(e)(2) AND 37 C.F.R. § 1.760

An application for the extension of patent term under 35 U.S.C. § 156 of U.S. Patent No. 4,626,538 (the '538 patent) was filed on October 5, 1999. The last day of the original patent term of the '538 patent is June 23, 2003.

In a letter dated December 3, 2002, the Food and Drug Administration (FDA) notified the Patent and Trademark Office (PTO) that the FDA considers its determination of the regulatory review period for SONATA® (zaleplon) to be final. In the event the PTO is unable to issue the certificate of patent term extension of the '538 patent before June 23, 2003, it is respectfully requested that an interim extension of 1 year be issued in accordance with 35 U.S.C. § 156(e)(2).

While no fees are considered necessary for this request for an interim extension, the Commissioner is hereby authorized to charge any fees that may be required to deposit account no. 01-1300.

Respectfully submitted,

Dated: March 21, 2003

By: _____

Arnold S. Milowsky
Attorney for Applicant
Reg. No. 35,288
Telephone: 610-902-2635

500557